

MATERIAL SAFETY DATA SHEET

1. SUBSTANCE AND SOURCE IDENTIFICATION

National Institute of Standards and Technology
Standard Reference Materials Program
100 Bureau Drive, Stop 2320
Gaithersburg, Maryland 20899-2320

SRM Number: 3243
MSDS Number: 3243
SRM Name: Ephedra-Containing Solid
Oral Dosage Form

Date of Issue: 20 March 2006

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Description: Standard Reference Material (SRM) 3243 consists of ten bottles of powdered ephedra-containing solid oral dosage form, each containing approximately 2.5 g of material.

Substance: Ephedra-Containing Solid Oral Dosage Form

2. COMPOSITION AND INFORMATION ON HAZARDOUS INGREDIENTS¹

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| Component: | Ephedrine |
| Other Designations: | Ephedrine (ephedrin; alpha-(1-(methylamino)ethyl)benzenemethanol; 1-phenyl-2-methylaminopropanol; 1-phenyl-1-hydroxy-2-methylaminopropane; 2-methylamino-1-phenyl-1-propanol; 1-hydroxy-2-methylamino-1-phenylpropane; natural ephedrine; alpha-hydroxy-beta-methylaminopropylbenzene) |
| CAS Number: | 299-42-3 |
| EC Number (EINECS): | 206-080-5 |
| SRM Nominal Concentration (mass %): | 1.12 |
| EC Classification: | Xn |
| EC Risk (R No.): | 22 |
| EC Safety (S No.): | 2, 22, 25 |
| Component: | Caffeine |
| Other Designations: | Caffeine (3,7-dihydro-1,3,7-trimethyl-1H-purine-2, 6-dione; trimethylxanthine; 1,3,7-trimethylxanthine; methyltheobromine; caffein; 7-methyltheophylline; 1,3,7-trimethyl-2,6-dioxopurine) |
| CAS Number: | 58-08-2 |
| EC Number (EINECS): | 200-362-1 |
| SRM Nominal Concentration (mass %): | 7.65 |
| EC Classification: | Xn |
| EC Risk (R No.): | 22 |
| EC Safety (S No.): | 2 |

¹Hazardous components 1 % or greater; Carcinogens 0.1 % or greater are listed in compliance with OSHA 29 CFR 1910.1200.

3. HAZARDS IDENTIFICATION

NFPA Ratings (Scale 0-4): Health = 1 Fire = 2 Reactivity = 0

Major Health Hazards: No significant target effects reported for ephedrine. Caffeine may aggravate eye disorders, gastrointestinal disorders, heart disorders, kidney disorders, and liver disorders.

Potential Health Effects

Inhalation: **Ephedrine:** Short-term exposure by inhalation may cause nausea, vomiting, irregular heartbeat, blurred vision, dilated pupils, lung congestion, convulsions or even a coma.

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| | Caffeine: Acute exposure may cause irritation to the nose and throat resulting in coughing and chest discomfort. | | | | | | | | | | | | |
| Skin Contact: | Ephedrine: Long-term exposure to the skin may cause a rash. Caffeine: Acute exposure may cause skin irritation. | | | | | | | | | | | | |
| Eye Contact: | Ephedrine: Short-term eye contact may cause dilated pupils and glaucoma. Caffeine: Acute exposure may cause eye irritation. | | | | | | | | | | | | |
| Ingestion: | Ephedrine: Short-term exposure by ingestion may cause allergic reactions, rash, nausea, vomiting, irregular heartbeat, headache, dizziness, disorientation, blurred vision, dilated pupils, lung congestion and convulsions. Caffeine: Ingestion of low concentrations may cause a small decrease in heart rate. Ingestion of large amounts may result in headache, lightheadedness, chills, fever, restlessness, nervousness, insomnia, constricted pupils, decreased visual fields, and gastrointestinal irritation, nausea, vomiting, stimulation of gastric acid secretion, abdominal cramps, diarrhea, and dehydration. Chronic exposure of caffeine may cause effects similar to acute exposure and heartburn, hyperventilation, low grade fever, respiratory failure, and cardiopulmonary arrest. Prolonged use may result in tolerance and physical dependence. | | | | | | | | | | | | |
| Listed as a Carcinogen/ Potential Carcinogen: | Ephedrine, Caffeine <table><tr><td>Yes</td><td>No</td><td></td></tr><tr><td>_____</td><td><u>X</u></td><td>In the National Toxicology Program (NTP) Report on Carcinogens.</td></tr><tr><td>_____</td><td><u>X</u></td><td>In the International Agency for Research on Cancer (IARC) Monographs.</td></tr><tr><td>_____</td><td><u>X</u></td><td>By the Occupational Safety and Health Administration (OSHA).</td></tr></table> | Yes | No | | _____ | <u>X</u> | In the National Toxicology Program (NTP) Report on Carcinogens. | _____ | <u>X</u> | In the International Agency for Research on Cancer (IARC) Monographs. | _____ | <u>X</u> | By the Occupational Safety and Health Administration (OSHA). |
| Yes | No | | | | | | | | | | | | |
| _____ | <u>X</u> | In the National Toxicology Program (NTP) Report on Carcinogens. | | | | | | | | | | | |
| _____ | <u>X</u> | In the International Agency for Research on Cancer (IARC) Monographs. | | | | | | | | | | | |
| _____ | <u>X</u> | By the Occupational Safety and Health Administration (OSHA). | | | | | | | | | | | |

4. FIRST AID MEASURES

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| Inhalation: | If adverse effects occur, remove to uncontaminated area. Give artificial respiration, if not breathing, by qualified personnel. Get immediate medical attention. |
| Skin Contact: | Rinse affected area with copious amounts of water for at least 15 minutes while removing contaminated clothing. Get medical attention, if needed. |
| Eye Contact: | Flush eyes, including under the eyelids, with copious amounts of water for at least 15 minutes. Get immediate medical attention. |
| Ingestion: | Get immediate medical attention. If vomiting occurs, keep head lower than hips to prevent aspiration. Give artificial respiration, if not breathing, by qualified personnel. |

5. FIRE FIGHTING MEASURES

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| Fire and Explosion Hazards: | Ephedrine is a moderate fire hazard. Caffeine is a slight fire hazard. |
| Extinguishing Media: | Regular dry chemical. Carbon dioxide. Water. Regular foam. |
| Fire Fighting: | Move container from fire area if it can be done without risk. Use extinguishing media appropriate for the surrounding fire. Wear full protective clothing and NIOSH-approved self-contained breathing apparatus (SCBA). |
| Component: | Ephedrine |
| Flash Point: | 85 °C (185 °F) |
| Method Used: | Not available. |
| Autoignition Temp.: | Not available. |
| Flammability Limits in Air | |
| UPPER (Volume %): | Not available. |
| LOWER (Volume %): | Not available. |

6. ACCIDENTAL RELEASE MEASURES

Occupational Release: Collect small spilled material in an appropriate container for disposal.

Disposal: Refer to Section 13, "Disposal Considerations".

7. HANDLING AND STORAGE

Storage: Store and handle in accordance with all current regulations and standards. Store in a cool, dry place.

Safe Handling Precautions: Use methods to minimize dust. See Section 8, "Exposure Controls and Personal Protection".

8. EXPOSURE CONTROLS AND PERSONAL PROTECTION

Exposure Limits: **Ephedrine:** No occupational exposure limits established.

Caffeine: No occupational exposure limits established.

Ventilation: Provide local exhaust ventilation system.

Respirator: If necessary, refer to the "NIOSH Guide to the Selection and Use of Particulate Respirators Certified under 42 CFR 84" for selection and use of respirators with organic vapor cartridges certified by NIOSH.

Eye Protection: Wear safety goggles. An eye wash station should be readily available near areas of use.

Personal Protection: Wear appropriate protective clothing and chemically resistant gloves to prevent skin exposure.

9. PHYSICAL AND CHEMICAL PROPERTIES

Component: **Ephedrine**

Appearance: Crystals. Colorless to white.

Relative Molecular Mass: 165.24

Molecular Formula: $C_6H_5CH(OH)CH(CH_3)NHCH_3$

Boiling Point: 255 °C (491 °F)

Melting Point: 34 °C – 40 °C (93 °F – 104 °F)

Water Solubility: 5 %

Solvent Solubility: Soluble in alcohol, ether, benzene, chloroform. Moderately soluble in mineral oils.

Component: **Caffeine**

Appearance and Odor: Crystalline powder. White. Odorless

Relative Molecular Mass: 194.19

Molecular Formula: $C_8H_{10}N_4O_2$

Boiling Point: Not applicable.

Melting Point: 238 °C (460 °F)

Water Solubility: 2.17 %

Solvent Solubility: Soluble in ethyl acetate, chloroform, pyrimidines, pyrrole, and tetrahydrofuran solution. Moderately soluble in alcohol and acetone. Slightly soluble in petroleum ether, ether, and benzene.

10. STABILITY AND REACTIVITY

Stability: X Stable Unstable

Stable at normal temperatures and pressure.

Conditions to Avoid: Avoid heat, flames, sparks, and other sources of ignition. Avoid contact with incompatible material.

Incompatible Materials: Oxidizing materials. Acids. Bases.

Fire/Explosion Information: See Section 5, "Fire Fighting Measures".

Hazardous Decomposition: Oxides of carbon. Nitrogen.

Hazardous Polymerization: _____ Will Occur X Will Not Occur

11. TOXICOLOGICAL INFORMATION

Route of Entry: X Inhalation X Skin X Ingestion

Toxicity Data: **Ephedrine**
 Man, Unreported LD_{LO}: 9 mg/kg
 Rat, Oral LD₅₀: 600 mg/kg

Caffeine
 Woman, Oral LD_{LO}: 400 mg/kg
 Woman, Intermittant-Oral TD_{LO}: 96 mg/kg (1 day)
 Man, Oral TD_{LO}: 13 mg/kg

Tumorigenic, Reproductive, Mutagenic Data: Ephedrine has been investigated as a reproductive effector. Caffeine has been investigated as a tumorigenic, mutagenic, and reproductive effector.

Health Effects (Acute and Chronic): See Section 3: "Hazards Identification" for potential health effects.

12. ECOLOGICAL INFORMATION

Ecotoxicity Data: Not available.

13. DISPOSAL CONSIDERATIONS

Waste Disposal: Dispose in accordance with all applicable federal, state, and local regulations.

14. TRANSPORTATION INFORMATION

U.S. DOT and IATA: Not regulated by DOT or IATA

15. REGULATORY INFORMATION

U.S. Regulations: CERCLA Sections 102a/103 (40 CFR 302.4): Not regulated.
 SARA Title III Section 302 (40 CFR 355.30): Not regulated.
 SARA Title III Section 304 (40 CFR 355.40): Not regulated.
 SARA Title III Section 313 (40 CFR 372.65): Not regulated.
 OSHA Process Safety (29 CFR 1910.119): Not regulated.
 SARA Title III Sections 311/312 Hazardous Categories (40 CFR 370.21):

ACUTE: Yes.
 CHRONIC: Yes.
 FIRE: Yes.
 REACTIVE: No.
 SUDDEN RELEASE: No.

State Regulations: California Proposition 65: Not regulated.

CANADIAN Regulations

WHMIS Classification: Not determined.

EUROPEAN Regulations

EC Classification (assigned): Xn Harmful.

EC Risk Phrases: R22 Harmful if swallowed.

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| EC Safety Phrases: | S2 | Keep out of reach of children. |
| | S22 | Do not breathe dust. |
| | S25 | Avoid contact with eyes. |
| National Inventory Status | | |
| U.S. Inventory (TSCA): | Ephedrine: | Listed on inventory. |
| | Caffeine: | Listed on inventory. |
| TSCA 12(b) | | |
| Export Notification: | Ephedrine: | Not listed. |
| | Caffeine: | Not listed. |

16. OTHER INFORMATION

Sources: MDL Information Systems, Inc., MSDS *Ephedrine*, 16 June 2005.
MDL Information Systems, Inc., MSDS *Caffeine*, 08 December 2005.

Disclaimer: Physical and chemical data contained in this MSDS are provided only for use as a guide in assessing the hazardous nature of the material. The MSDS was prepared carefully, using current references; however, NIST does not certify the data in the MSDS. The certified values for this material are given in the NIST Certificate of Analysis.